In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-1315V
Filed: April 16, 2025

ROBERT BEN,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Special Master Horner

Bradley S. Freedberg, Bradley S. Freedberg, P.C., Denver, CO, for petitioner.
Parisa Tabassian, U.S. Department of Justice, Washington, DC, for respondent.

DECISION[1]

On May 5, 2021, petitioner filed a petition under the National Childhood Vaccine Injury Act, 42 U.S.C. § 300aa-10, *et seq.* (2012),[2] alleging that he suffered chronic inflammatory polyneuropathy ("CIP") following receipt of an influenza ("flu") vaccination on December 19, 2019.[3] (ECF No. 1.) In an amended petition, he alleged that his

[1] Because this document contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the document will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] All references to "§ 300aa" below refer to the relevant section of the Vaccine Act at 42 U.S.C. § 300aa-10-34.

[3] The initial petition alleged petitioner received the flu vaccine on November 13, 2019, based on citation to petitioner's affidavit. (ECF No. 1.) In an amended petition, petitioner alleged that the flu vaccination at issue was administered on December 13, 2019, citing a vaccine administration record at Exhibit 6. (ECF No. 23.) However, in a further amended petition, petitioner alleged he received the flu vaccine on December 19, 2019, again citing Exhibit 6. (ECF No. 30.) In a subsequent amended petition, petitioner alleged the vaccine was administered on December 13, 2019, citing the same administration record. (ECF No. 40.) Ultimately, in his motion for a ruling on the written record, petitioner asserts the vaccination

condition constituted chronic inflammatory demyelinating polyneuropathy ("CIDP") caused-in-fact by his vaccination. (ECF No. 40, p. 2.) Ultimately, petitioner argues that he either suffered a Table Injury of Guillain-Barré Syndrome ("GBS") or CIDP caused-in-fact by his vaccination. (ECF No. 70, pp. 2-3.) For the reasons discussed below, I find that petitioner is *not* entitled to an award of compensation.

I. Applicable Statutory Scheme

Under the National Vaccine Injury Compensation Program, compensation awards are made to individuals who have suffered injuries after receiving vaccines. In general, to gain an award, a petitioner must make a number of factual demonstrations, including showing that an individual received a vaccination covered by the statute; received it in the United States; suffered a serious, long-standing injury; and has received no previous award or settlement on account of the injury. Finally – and the key question in most cases under the Program – the petitioner must also establish a *causal link* between the vaccination and the injury.

In some cases, the petitioner may simply demonstrate the occurrence of what has been called a "Table Injury." That is, it may be shown that the vaccine recipient suffered an injury of the type enumerated in the "Vaccine Injury Table," corresponding to the vaccination in question, within an applicable time period following the vaccination also specified in the Table. If so, the Table Injury is presumed to have been caused by the vaccination unless it is affirmatively shown that the injury was caused by some factor other than the vaccination. § 300aa-13(a)(1)(A); § 300aa-11(c)(1)(C)(i); § 300aa-14(a); § 300aa-13(a)(1)(B). In many cases, however, the vaccine recipient may have suffered an injury *not* of the type covered in the Vaccine Injury Table. In such instances, an alternative means exists to demonstrate entitlement to a Program award. That is, the petitioner may gain an award by showing that the recipient's injury was "caused-in-fact" by the vaccination in question. § 300aa-13(a)(1)(B); § 300aa-11(c)(1)(C)(ii). In that context, the presumptions available under the Vaccine Injury Table are inoperative. The burden is on the petitioner to introduce evidence demonstrating that the vaccination actually caused the injury in question. *Althen v. Sec'y of Health & Human Servs.*, 418 F.3d 1274, 1278 (Fed. Cir. 2005); *Hines ex rel. Sevier v. Sec'y of Health & Human Servs.*, 940 F.2d 1518, 1525 (Fed. Cir. 1991).

GBS is a Table injury if onset occurs 3-42 days following receipt of a flu vaccine. 42 C.F.R. § 100.3(a)(XIV)(D). However, respondent observed that petitioner asserts that he suffered chronic inflammatory demyelinating polyneuropathy ("CIDP"), which is not a Table Injury. Moreover, a diagnosis of CIDP is listed among the exclusionary criteria for a Table Injury of GBS. 42 C.F.R. § 100.3(c)(15)(vi). To succeed on a claim that petitioner's flu vaccine caused CIDP, petitioner must satisfy the burden of proof for "causation-in-fact."

---

was administered on December 19, 2019. (ECF No. 67, p. 3.) Exhibit 6 indicates the vaccine was administered on December 19, 2019.

The showing of "causation-in-fact" must satisfy the "preponderance of the evidence" standard, the same standard ordinarily used in tort litigation. § 300aa-13(a)(1)(A); *see also Althen*, 418 F.3d at 1279; *Hines*, 940 F.2d at 1525. Under that standard, the petitioner must show that it is "more probable than not" that the vaccination was the cause of the injury. *Althen*, 418 F.3d at 1279. The petitioner need not show that the vaccination was the sole cause but must demonstrate that the vaccination was at least a "substantial factor" in causing the condition, and was a "but for" cause. *Shyface v. Sec'y of Health & Human Servs.*, 165 F.3d 1344, 1352 (Fed. Cir. 1999). Thus, the petitioner must supply "proof of a logical sequence of cause and effect showing that the vaccination was the reason for the injury[,]" with the logical sequence being supported by "reputable medical or scientific explanation." *Althen*, 418 F.3d at 1278; *Grant v. Sec'y of Health & Human Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Ultimately, petitioner must satisfy what has come to be known as the *Althen* test, which requires: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of proximate temporal relationship between vaccination and injury.[4] *Id*.

A petitioner may not receive a Vaccine Program award based solely on his or her assertions, but may support the petition with either medical records or by the opinion of a competent physician. § 300aa-13(a)(1). Medical records are generally viewed as particularly trustworthy evidence, because they are created contemporaneously with the treatment of the patient. *Cucuras v. Sec'y of Health & Human Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). However, medical records and/or statements of a treating physician's views do not *per se* bind the special master to adopt the conclusions of such an individual, even if they must be considered and carefully evaluated. § 300aa-13(b)(1). A petitioner may rely upon circumstantial evidence. *Althen*, 418 F.3d at 1280. In that regard, the *Althen* court noted that a petitioner need not necessarily supply evidence from medical literature supporting petitioner's causation contention, so long as the petitioner supplies the medical opinion of an expert. *Id*. at 1279-80. While scientific certainty is not required, that expert's opinion must be based on "sound and reliable" medical or scientific explanation. *Boatmon v. Sec'y of Health & Human Servs*., 941 F.3d 1351, 1359 (Fed. Cir. 2019).

Cases in the Vaccine Program are assigned to special masters who are responsible for "conducting all proceedings, including taking such evidence as may be

[4] Additionally, petitioner alternatively argues that his vaccination may have significantly aggravated his condition. (ECF No. 70, p. 3.) Where a petitioner in an off-Table case is seeking to prove that a vaccination aggravated a preexisting injury, the petitioner must establish the three *Althen* prongs along with three additional factors described in the prior *Loving* case. *See Loving v. Sec'y of Health & Human Servs.*, 86 Fed. Cl. 135, 144 (2009) (combining the first three *Whitecotton* factors for claims regarding aggravation of a Table injury with the three *Althen* factors for off table injury claims to create a six-part test for off-Table aggravation claims); *see also W.C. v. Sec'y of Health & Human Servs*., 704 F.3d 1352, 1357 (Fed. Cir. 2013) (applying the six-part *Loving* test). The additional *Loving* factors require petitioners to demonstrate aggravation by showing: (1) the vaccinee's condition prior to the administration of the vaccine, (2) the vaccinee's current condition, and (3) whether the vaccinee's current condition constitutes a "significant aggravation" of the condition prior to the vaccination. *Loving*, 86 Fed. Cl. at 144.

appropriate, making the requisite findings of fact and conclusions of law, preparing a decision, and determining the amount of compensation, if any, to be awarded." Vaccine Rule 3. Special masters must ensure each party has had a "full and fair opportunity" to develop the record but are empowered to determine the format for taking evidence based on the circumstances of each case. Vaccine Rule 3(b)(2); Vaccine Rule 8(a); Vaccine Rule 8(d). Special masters are not bound by common law or statutory rules of evidence but must consider all relevant and reliable evidence in keeping with fundamental fairness to both parties. Vaccine Rule 8(b)(1). The special master is required to consider "all [] relevant medical and scientific evidence contained in the record," including "any diagnosis, conclusion, medical judgment, or autopsy or coroner's report which is contained in the record regarding the nature, causation, and aggravation of the petitioner's illness, disability, injury, condition, or death," as well as the "results of any diagnostic or evaluative test which are contained in the record and the summaries and conclusions." § 300aa-13(b)(1)(A). The special master is required to consider the entirety of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler v. Sec'y of Health & Human Servs.*, 88 F.4th 958, 963 (Fed. Cir. 2023) (citing *Hines*, 940 F.2d at 1528).

II. Procedural History

Petitioner filed medical records and affidavits marked as Exhibits 1-9[5] as well as two amended petitions (ECF Nos. 23, 30) between May of 2021 and June of 2022. The case was reassigned to the undersigned in January of 2022. (ECF Nos. 28-29.) Respondent filed his Rule 4(c) Report on August 19, 2022. (ECF No. 39.) Respondent contended that petitioner's medical records lacked the medical opinion necessary to implicate his flu vaccine as a cause of CIDP, but also contended that his condition was in any event diabetic neuropathy rather than CIDP. (*Id*. at 10-11.)

Thereafter, the parties exchanged expert reports, with neurologist Avinoam Shuper, M.D., opining for petitioner and neurologist Pria Anand, M.D., opining for respondent. (ECF Nos. 44, 47, 53-54; Exs. 10, 13-25; A-B.) During this period, petitioner also filed a signed declaration and EMG results. (ECF Nos. 48, 50; Exs. 11-12.) I then issued a Rule 5 order. (ECF No. 52.) Petitioner was permitted to file a further report responding to Dr. Anand's report (*Id.* at 3); however, Dr. Shuper became unavailable. (ECF Nos. 58-59.) Petitioner then filed an additional report by Garry Ruben, M.D., a general and vascular surgeon. (ECF No. 65; Exs. 26-27.)

A follow up status conference was held on January 30, 2024. (ECF No. 66.) During the status conference, respondent's counsel requested that Dr. Ruben's report be struck. (*Id.* at 1.) That request was denied, and the parties otherwise agreed that

[5] In the undersigned's Initial Order, petitioner was directed to file certified copies of the medical records filed as Exhibits 5 & 6. (ECF No. 33, p. 2.) Petitioner subsequently re-filed Exhibit 6, which constituted a certified copy of his vaccine administration records, and also filed Exhibit 9, which he indicated represented a certified copy of his full University of Colorado Health medical record from January 1, 2016 through February 28, 2022. (ECF Nos. 34, 37.) However, Exhibit 9 does not include all the records contained in Exhibits 5. Therefore, this decision at turns cites to Exhibit 9 and Exhibit 5 even though they largely include the same records.

the case was ripe for resolution the written record pursuant to Vaccine Rule 8(d). (*Id.*) Petitioner filed a motion for a ruling on the written record in February of 2024 and the motion was fully briefed as of April 8, 2024. (ECF Nos. 67, 69-70.)

I have concluded that the parties have had a full and fair opportunity to develop the record and that it is appropriate to resolve this case without an entitlement hearing. S*ee Kreizenbeck v. Sec'y of Health & Human Servs*., 945 F.3d 1362, 1366 (Fed. Cir. 2020) (citing *Simanski v. Sec'y of Health & Human Servs*., 671 F.3d 1368, 1385 (Fed. Cir. 2012)); *see also* Vaccine Rule 8(d); Vaccine Rule 3(b)(2).

III. Factual Summary

a. As reflected in the medical records

i. Pre-vaccination history

Petitioner's relevant pre-vaccination medical history includes uncontrolled type 2 diabetes, diabetic peripheral neuropathy, and neurotrophic foot ulcerations. (Ex. 4, pp. 7-8; Ex. 5, p. 576; Ex. 7, pp. 8-21, 26-28; Ex. 8, pp. 173-238; Ex. 9, pp. 1093, 1116-18, 1120.)

In November of 2015, petitioner developed foot ulcers and received podiatric care. (Ex. 7, p. 27.) His podiatrist assessed "[p]lantar left greater than right first metatarsal head, pressure induced, grade 1 neurotrophic ulcerations" and "[s]evere diabetic peripheral neuropathy." (*Id.* at 28.) In June of 2016, he developed cellulitis in his right foot which quickly resolved with antibiotics. (*Id.* at 13-14.) Petitioner received regular podiatric care for his neurotrophic ulcerations through September of 2016. (*Id.* at 10-21, 26.)

On November 30, 2018, petitioner visited a primary care provider with concerns that his diabetic ulcer, which he reported having for more than a year, was getting worse and might be infected. (Ex. 4, p. 7.) The treating provider documented petitioner's history of diabetic neuropathy. (*Id.*) Petitioner noted that while he had seen a podiatrist for his diabetic foot ulcers, he had not followed up in months. (*Id.*) Additionally, petitioner reported that he does not check his blood sugar and that he had not obtained labs to evaluate his diabetes in over two years. (*Id.*) The primary care provider referred petitioner to a wound care clinic for debridement and a more thorough assessment. (*Id.*)

Petitioner presented for wound care for his foot ulcerations in December of 2018. (Ex. 8, p. 233.) The wound care nurse noted petitioner's history of diabetic neuropathy and petitioner was diagnosed with diabetic foot ulcers. (*Id.* at 233, 238.) At his initial wound care appointment, petitioner reported that he had not been checking his blood glucose. (*Id.* at 233.) Petitioner continued to receive regular wound care for his neurotrophic ulcers through February 2019. (*Id.* at 173-231.) At his wound care appointment in February of 2019, the treating provider remarked that petitioner's foot

ulcers were not healing, petitioner was "not adhering to treatment plan," and that petitioner was at risk for infection and potential amputation of his toe(s) and/or feet. (*Id.* at 173.) In June of 2019, petitioner returned for podiatric care. (Ex. 7, p. 9.) Again, the podiatrist assessed "acute-on-chronic" pressure-induced neurotrophic foot ulcerations and diabetic peripheral neuropathy. (*Id.*)

On September 16, 2019, petitioner returned to his primary care provider for a follow up of his diabetes management. (Ex. 4, p. 11.) Petitioner admitted that "I need to get my A1c under better control" and reported he had not been checking his blood sugar or adhering to his diet very well. (*Id.*) His provider noted that the last time petitioner was seen, his A1c levels indicated that his diabetes was very poorly controlled. (*Id.*) Additionally, his provider documented that petitioner had "re-developed ulcers on both feet" and encouraged him to return to the wound care clinic. (*Id.*) Petitioner indicated his commitment to getting his diabetes under control. (*Id.*)

Three days later, petitioner returned to the wound care clinic for evaluation "of the same bilateral plantar foot wounds that patient was last seen for at the wound clinic." (Ex. 8, p. 140.) The wound care nurse again noted petitioner's history of diabetic neuropathy and diabetic foot ulcerations. (*Id.*) At his wound care clinic appointments, his treating providers stressed the importance of controlling his diabetes in order to promote wound healing and manage his diabetic neuropathy. (*Id.* at 141.) Petitioner continued to regularly visit the wound care clinic for management and treatment of his foot ulcerations until being discharged from the clinic on August 31, 2020. (*Id.* at 7-140.)

Petitioner established care with primary care provider Brien Whittington, D.O., on September 27, 2019. (Ex. 5, p. 576.) In documenting petitioner's history, Dr. Whittington noted that "[u]nfortunately over the past several years patient has been ignoring his diabetes and his sugars have been out of control." (*Id.*) Petitioner reported experiencing numbness in his feet. (*Id.*)

From October 27, 2019 to November 14, 2019, petitioner was hospitalized after presenting to the emergency department with progressively worsening edema in his lower extremities and a few week history of shortness of breath. (Ex. 9, pp. 1093, 1103.) While admitted, he underwent a quadruple coronary artery bypass graft surgery on November 4, 2019. (*Id.* at 1549.) During his hospitalization, petitioner reported experiencing neuropathy in his feet and cold and tingly hands. (*Id.* at 1118.) Petitioner was assessed with diabetic neuropathy during his hospitalization. (*Id.* at 1116.) After his discharge from the hospital, petitioner returned to the podiatrist for management of his neurotrophic ulcers. (Ex. 7, p. 2.) The podiatrist assessed severe bilateral diabetic peripheral neuropathy and referred petitioner for routine diabetic foot care. (*Id.*)

ii. Vaccination & post-vaccination history

On December 19, 2019, petitioner received the flu vaccine at issue. (Ex. 6, p. 3.) In January of 2020, petitioner underwent an insertion of an implantable cardioverter-

defibrillator ("ICD") to manage his cardiomyopathy. (Ex. 9, pp. 1037-38.) At a follow-up cardiology appointment on February 25, 2020, petitioner first reported that he began experiencing "vague weakness in both hands" after his surgery. (Ex. 5, p. 1244.) As a result, petitioner was referred to neurology. (*Id.*)

On March 10, 2020, petitioner was seen by neurologist Erin Stewart, M.D. (Ex. 5, p. 1232.) Under review of systems, Dr. Stewart documented that petitioner was positive for weakness and numbness. (*Id.* at 1235.) She diagnosed petitioner with weakness in both hands and polyneuropathy associated with underlying disease. (*Id.* at 1238.) Dr. Stewart ordered a cervical spine CT, which petitioner underwent on March 15, 2020. (Ex. 9, p. 1020.) The CT revealed mild C4-C5 to C6-C7 cervical spondylosis and multiple thyroid nodules. (*Id.* at 1021.) She also referred petitioner for an EMG of his upper extremities. (Ex. 5, p. 1165.)

Petitioner had a video visit with neurologist Hamid Mortazavi, M.D., on April 16, 2020. (Ex. 5, p. 1206.) He reported neck stiffness, vision problems, trouble walking, and numbness. (*Id.* at 1210.) In documenting the review of systems, Dr. Mortazavi noted that petitioner stated that he sometimes feels dizzy when standing up and that he was experiencing weakness. (*Id.*) Dr. Mortazavi also referred petitioner for an EMG. (*Id.* at 1206.)

On May 12, 2020, petitioner was seen by neurologist Kevin Scott, M.D., for electrodiagnostic testing of the upper extremities to evaluate for possible neuromuscular disease. (Ex. 5, pp. 1165, 1169.) The neurological exam showed "muscle atrophy and weakness of both hands with depressed pinprick sensation principally in the ulnar nerve distribution." (*Id.* at 1169.) The results of petitioner's EMG were most consistent with "bilateral, severe, chronic, median mononeuropathies at both wrists" and "a severe, subacute to chronic, likely acquired, sensorimotor polyneuropathy with demyelinating features." (*Id.*)

Petitioner was seen by Dr. Scott on June 26, 2020 for a full neurologic evaluation. (Ex. 5, p. 1116.) In documenting petitioner's medical history, Dr. Scott remarked that petitioner was in his "usual state of health" until November of 2019 when petitioner underwent cardiac surgery. (*Id.* at 1120.) He noted that "[p]ostoperatively, [petitioner] developed rapidly progressive weakness, numbness, and muscle atrophy of the upper and lower extremities." (*Id.*) While Dr. Scott documented that petitioner had a history of "poorly controlled" diabetes, he indicated that petitioner's management of his diabetes had improved. (*Id.*) Dr. Scott's physical examination of petitioner revealed "length dependent weakness of the upper and lower extremities with atrophy and profound weakness of the hands." (*Id.* at 1124.) Weakness was noted in petitioner's triceps, deltoids, biceps, hip flexors, dorsiflexors, and great toe extension. (*Id.*) Dr. Scott observed "[l]ength dependent sensory changes to the knees and wrists involving all modalities." (*Id.*) Additionally, the physical examination revealed that petitioner's reflexes were absent throughout and an unsteady tandem gait. (*Id.*) Dr. Scott diagnosed petitioner with CIDP. (*Id.* at 1127.) In documenting his clinical impression, Dr. Scott opined that petitioner's muscle atrophy and weakness were solely due to his

CIDP while petitioner's sensory loss was caused by a combination of his diabetes and CIDP. (*Id.* at 1124.) To address his neuropathic symptoms, Dr. Scott prescribed petitioner CellCept[6] and IVIg[7] treatment. (*Id.*)

Petitioner was seen by his primary care provider on December 16, 2020. (Ex. 5, p. 779). Dr. Whittington documented that petitioner experiences peripheral neuropathy in both feet with numbness in his toes bilaterally. (*Id.* at 783.) In his assessment of petitioner, Dr. Whittington remarked "[u]nfortunately patient received a flu vaccine and developed Guillain-Barré syndrome." (*Id.*) However, CIDP, and not GBS, was listed as the visit diagnosis. (*Id.* at 783, 788.)

On December 28, 2020, petitioner followed up with Dr. Scott for management of his neurological symptoms. (Ex. 5, pp. 765, 769.) In documenting petitioner's history of CIDP, Dr. Scott noted that petitioner "[s]till has weakness of the hands; however, they feel less cold and somewhat stronger. Describes intermittent lancinating pain involving the distal lower extremities that comes and goes without clear triggers." (*Id.* at 769.) Dr. Scott documented that petitioner's muscle strength had improved relative to his last exam with petitioner showing normal strength in his deltoid and bicep muscles with mild to moderate weakness in his triceps and moderate weakness in both of his hands. (*Id.* at 773.) His hip flexor strength and knee extensors also appeared normal. (*Id.*) However, petitioner's reflexes remained absent throughout and his tandem gait remained unsteady. (*Id.*) The plan was for petitioner to continue with IVIg and CellCept treatments. (*Id.*)

At a follow up appointment in June of 2021, Dr. Scott remarked that petitioner's "presentation remains complex with features of severe diabetic polyneuropathy as well as CIDP." (Ex. 5, p. 3007.) He noted that petitioner "has made significant clinical improvement which is likely multifactorial," crediting his IVIg and immunosuppression treatment as well as petitioner's significant efforts to get his diabetes under control. (*Id.*) Dr. Scott's clinical impression that petitioner's muscle atrophy and weakness were solely caused by his CIDP remained unchanged. (*Id.* at 3011.) In light of petitioner's clinical improvements, Dr. Scott discontinued petitioner's IVIg treatment but instructed him to continue taking CellCept. (*Id.* at 3007.)

Petitioner continued to have other significant medical issues and was hospitalized three times throughout June of 2021 and September of 2021. (Ex. 9, pp.

---

[6] CellCept is a trademark preparation of mycophenolate mofetil which is an immunosuppressive agent that weakens or diminishes the immune response. *CellCept*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=8496 (last visited Apr. 3, 2025); *Mycophenolate mofetil*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=32633 (last visited Apr. 3, 2025); *Immunosuppression*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=24939 (last visited Apr. 3, 2025).

[7] IVIg is the intravenous administration of immunoglobulin – "any of the structurally related glycoproteins that function as antibodies." *Immunoglobulin*, DORLAND'S MEDICAL DICTIONARY ONLINE, https://www.dorlandsonline.com/dorland/definition?id=24894 (last visited Apr. 3, 2025).

30-33, 280-84, 545-47.) Petitioner also continued to follow up with Dr. Scott in November and December of 2021. (Ex. 5, p. 2279, 2342.) At these follow ups, petitioner reported right upper extremity weakness as well as increasing weakness in both his upper and lower extremities. (*Id.* at 2282, 2343.) Dr. Scott remarked that this increased weakness in his extremities "may be sequelae of his most recent large vessel stroke superimposed upon baseline diabetes, heart disease, and neuropathy." (*Id.* at 2283.) Subsequently, petitioner underwent another EMG of his upper extremities. (*Id.* at 2263, 2267.) The study revealed "severe sensorimotor polyneuropathy with mixed axonal and demyelinating features" and a "[p]ossible conduction block right median nerve." (*Id.* at 2267.) Dr. Scott advised petitioner to continue taking CellCept but also instructed petitioner to restart his IVIg treatments. (*Id.*) Additionally, Dr. Scott referred petitioner to rehabilitation for evaluation of his weakness in his extremities and balance issues, and petitioner began physical therapy on December 14, 2021. (*Id.* at 2250, 2255.)

b. As reflected in affidavits

The record reflects four accounts by petitioner of the events at issue.

In a sworn affidavit dated February 25, 2021, petitioner recounted that he was in good health prior to receipt of a seasonal flu vaccine at the University of Colorado hospital (UC Health) on or about November 13, 2019. (ECF No. 27.) Petitioner indicated that he first noticed coldness in his hands and weakness in his fingers, with gradual loss of sensation in his hands, during physical therapy following his November 4, 2019 cardiac surgery. (*Id*.) He indicated that his condition gradually worsened to the point that he could no longer use his hands and had difficulty walking, prompting him to visit an urgent care neurologist in April of 2020. (*Id.*) Petitioner was subsequently diagnosed with CIDP. (*Id*.)

In a second statement filed January 19, 2022 (styled as an affidavit, but neither sworn nor dated), petitioner indicated "I was in good health when I received a seasonal influenza vaccine at a University of Colorado hospital (UC Health) on or about December 19, 2019." (ECF No. 31-1.)

Within petitioner's expert report by Dr. Shuper, which was filed on November 18, 2022, there is a screen capture of a narrative statement by petitioner. (Ex. 10, p. 7.) The source of this statement is unclear, and it is not dated. That statement indicates that "[a]fter vaccination, I could not perform many non-work activities that I enjoyed before vaccination." (*Id.*) He indicates that "[a] few weeks after I received the vaccination, I started noticing that both my hands had lost all of my hand muscles." (*Id*.) The statement goes on to describe a number of things petitioner can no longer do following vaccination. (*Id.*) However, it does not identify the date of vaccination. This statement does not explain the progression of petitioner's symptoms, only expressing the distinction between what petitioner could do before and after vaccination and does not discuss what care petitioner sought as a result.

Finally, petitioner submitted a "to whom it may concern" letter dated April 4, 2023. (ECF No. 50; Ex. 12.) In that letter, petitioner indicated that he was hospitalized for his cardiac surgery from October 27, 2019, to November 14, 2019, and that he received the flu vaccination at issue on the last day of his hospitalization. (Ex. 12.) He indicated that he began his cardiac rehabilitation on November 19, 2019, and that "about 2 1/2 weeks into it, I felt more unbalanced and a slight curl to both my pinky fingers, they were symmetrical, but [I] wasn't sure what it could be. I had an appointment with Dr. Strater [*sic*] my cardiologist in late December, I showed him my fingers and my balance . . . ." (*Id*.)

IV. Expert Medical Opinions

a. Petitioner's Neurology Expert, Avinoam Shuper, M.D.[8]

Dr. Shuper suggests that nervous system disorders have been linked to vaccination dating back to the observation of a neuroparalytic syndrome following Louis Pasteur's rabies vaccine. (Ex. 10, p. 2.) He discusses GBS, and especially GBS following the 1976-77 swine flu vaccination campaign, as a prime example of this phenomenon. (*Id*.) Because GBS is a syndrome with several sub-types, it is best understood broadly as "an acute disease manifested by demyelinating polyneuropathy." (*Id*. at 4.) Although CIDP has emerged as a distinct diagnosis from GBS, there is a "close resemblance" between the two conditions. (*Id*. at 5-6.) The primary distinction is the duration of onset, with CIDP generally developing over eight or more weeks while GBS onset occurs more acutely, typically in less than four weeks. (*Id*. at 6.) Thus, Dr. Shuper opines that there is a "consensus" in the medical literature that these conditions exist as part of a spectrum of disorders falling under the category of "inflammatory neuropathies." (*Id*.)

Dr. Shuper acknowledges that it remains unproven how a vaccine can cause an inflammatory neuropathy. (Ex. 10, p. 10.) However, he proposes that antibodies formed in response to the vaccine may lead to autoimmune attack on different sites of the peripheral nervous system, explaining the overall spectrum of clinical presentations. (*Id*. at 10-11.) Dr. Shuper relies, in particular, on a figure from Swaiman's Textbook of Pediatric Neurology[9] illustrating how campylobacter jejuni can cause an immune

[8] Dr. Shuper is a neurologist who serves as a Clinical Professor Emeritus at the Faculty of Medicine, Clinical Departments at the University of Tel Aviv. (Ex. 13.) Previously, Dr. Shuper worked as a neurologist at the Schneider Children's Medical Center in Petah Tikva, Israel, and served as its Director of Pediatric Neurology. (Ex. 10, p. 1.) He has conducted extensive research and published peer reviewed articles on various neurological conditions, including epilepsy, neurofibromatosis, seizure disorder, and electroencephalography. (Ex. 13.) Dr. Shuper has authored over 117 articles, including nine reviewed articles, and has previously offered expert testimony in the Program. (*Id.*)

[9] Dr. Shuper cited to and included a figure from Swaiman's Pediatric Neurology textbook in his expert report. (Ex. 10, pp. 8-9.) A full citation to the textbook was not included in his expert report. (*Id.*) Additionally, no copy of the publication was filed as an exhibit by petitioner. Therefore, the information included in Dr. Shuper's expert report is the only information the court was provided regarding the reference to Swaiman's Pediatric Neurology textbook.

reaction resulting in molecular mimicry to gangliosides and ultimately injury in the form of axonal damage or demyelination of the peripheral nerves. (*Id*. at 9-10.) Dr. Shuper opines that it is reasonable to infer vaccine causation when a vaccination precedes onset of neuropathy by no more than six weeks. (*Id*. at 14.)

In petitioner's case, Dr. Shuper opines that petitioner developed an inflammatory neuropathy that first presented as GBS, but ultimately progressed to CIDP. (Ex. 10, p. 14.) Dr. Shuper credits a narrative description by petitioner regarding the onset of his condition.[10] (*Id*. at 6-7.) Thus, he opines that, after petitioner initially attempted to manage his vaccine side-effect himself, he first complained of the symptoms that would ultimately be diagnosed as GBS and then CIDP during a February 2020 cardiology follow-up. (*Id*. at 7-8 (citing Ex. 5, p. 1244).) Dr. Shuper acknowledges that petitioner reported numbness in his feet in September of 2019 (citing Ex. 5, p. 576), as well as cold, tingling sensations in his hands in November of 2019 (citing Ex. 2, p. 153), but contends that these symptoms are distinct from the hand weakness that petitioner reported post-vaccination. (Ex. 10, p. 8.)

Dr. Shuper indicated that "I can understand if other expert witnesses review the same evidence and come away with the conclusion that diabetes, or some other condition, played a more substantial role in causing his CIDP to develop. However, I believe the medical records still show that, even from that perspective, the influenza vaccination played at least a substantial rose in causing his CIDP to develop and/or aggravating its symptoms." (Ex. 10, p. 9.) Specifically, he opines petitioner suffered CIDP caused by his flu vaccination for four reasons: (1) the flu vaccine can cause both GBS and GBS-like conditions such as CIDP; (2) there was a short time interval between the vaccination and the first symptoms of petitioner's condition, which constitutes a "first indication of a causal connection"; (3) petitioner's reported symptoms pre- and post-vaccination were distinct; and (4) "there is a well-researched mechanism behind vaccine-induced CIDP." (*Id*. at 7-9.)

According to Dr. Shuper, "[a]n association between CIDP and diabetes has been acknowledged for several decades, but the nature of this association, and whether it involves a causal relationship, remains poorly recognized, owing to the concurrent existence of a typical diabetic neuropathy in many patients." (Ex. 10, p. 11.) Dr. Shuper cites several studies supporting increased incidences of CIDP among diabetic patients,[11] but also cites one study that suggested there was no association. (*Id*. at 13

[10] Dr. Shuper's report contains a screen capture of a document containing a first-hand account purportedly by petitioner (Ex. 10, p. 7), which is separately described in section (III)(b), *supra*; however, Dr. Shuper does not provide any citation or indicate from where he pulled this description of events. The account is not excerpted from any of the signed statements that petitioner otherwise filed. (*See* ECF No. 27; ECF No. 31-1; Ex. 12.)

[11] Citing C. Vital et al., *Relapsing Inflammatory Demyelinating Polyneuropathy in a Diabetic Patient*, 71 ACTA NEUROPATHOLOGICA 94 (1986) (Ex. 17); Francisco T. Rotta et al., *The Spectrum of Chronic Inflammatory Demyelinating Polyneuropathy*, 173 J. NEUROLOGICAL SCIS. 129 (2000) (Ex. 18); Pierre Lozeron et al., *Symptomatic Diabetic & Non-Diabetic Neuropathies in a Series of 100 Diabetic Patients*, 249 J. NEUROLOGY 569 (2002) (Ex. 19); Khema R. Sharma et al., *Demyelinating Neuropathy in Diabetes Mellitus*, 59 ARCHIVES NEUROLOGY 758 (2002) (Ex. 20); Yusuf A. Rajabally et al., *Epidemiologic Variability*

(citing A. Chiò et al., *Comorbidity Between CIDP & Diabetes Mellitus: Only a Matter of Chance?*, 16 EURO. J. NEUROLOGY 752 (2009) (Ex. 24)).) Ultimately, he opines that the association between diabetes and CIDP is "well-founded." (*Id*. at 13.) He explains that a number of neuropathies are seen in diabetic patients, including distal symmetric polyneuropathy most commonly, but also inflammatory neuropathies including CIDP, radiculoplexus neuropathies and vasculitic multiple mononeuropathies. (*Id*.)

"Diagnosis of CIDP in the presence of diabetes can be made mainly on the basis of clinical characteristics and specific electrophysiological criteria; cerebrospinal fluid analysis, imaging and neuropathology are occasionally helpful." (Ex. 10, p. 13.) In petitioner's case, Dr. Shuper opines that neither the clinical characteristics nor the specific electrophysiological criteria for diabetes related CIDP are present. (*Id.*) Thus, he stresses that petitioner was never diagnosed as having diabetes related CIDP. (*Id*.) Further, he opines that "[e]ven if another neurologist were to disagree, and perhaps argue that the record does not clearly establish that diabetes could not have been a factor in the development of [petitioner]'s CIDP, I believe that on the basis of these records, one may still conclude, with a reasonable degree of medical certainty, that the influenza vaccination also played a significant role in the development of [petitioner]'s CIDP." (*Id*.) (However, Dr. Shuper did not delineate the clinical characteristics or electrophysiologic criteria informing this point. Nor did he explicitly explain how diabetes and the flu vaccine would have acted concurrently to cause CIDP.)

b. Respondent's Neurology Expert, Pria Anand, M.D.[12]

Dr. Anand acknowledges that a diagnosis of CIDP "cannot be entirely ruled out." (Ex. A, pp. 3-4.) However, she assesses petitioner as having "severe" and

---

of Chronic Inflammatory Demyelinating Polyneuropathy with Different Diagnostic Criteria: Study of a UK Population, 39 MUSCLE & NERVE 432 (2009) (Ex. 21); M. Mahdi-Rogers & R.A.C. Hughes, *Epidemiology of Chronic Inflammatory Neuropathies in Southeast England*, 21 EUR. J. NEUROLOGY 28 (2014) (Ex. 22); Vera Bril et al., *The Dilemma of Diabetes in Chronic Inflammatory Demyelinating Polyneuropathy*, 30 J. DIABETES & ITS COMPLICATIONS 1401 (2016) (Ex. 23); Yusuf A. Rajabally et al., *CIDP & Other Inflammatory Neuropathies in Diabetes Diagnosis & Management*, 13 NATURE REVS. NEUROLOGY 599 (2017) (Ex. 25).

[12] Dr. Anand received her medical degree from Stanford University in 2014. (Ex. B, p. 1.) She completed her internship in internal medicine in 2015 at the University of North Carolina Hospital and Clinics in Chapel Hill. (*Id.*) In 2018, she completed her residency in neurology at John Hopkins Hospital in Baltimore, where she served as the Executive Chief Resident. (*Id.*; Ex. A, p. 1.) Thereafter, Dr. Anand completed her fellowship in neuroimmunology, neuro-infectious diseases, and advanced general neurology at Massachusetts General Hospital in Boston. (Ex. A, p. 1.; Ex. B, p. 1.) Since completing her fellowship, Dr. Anand has served as an attending physician, an assistant professor of neurology, and the Chief of the Division of Hospitalist Neurology at Boston University School of Medicine and the Boston Medical Center. (Ex. B, p. 1.) She is board certified in neurology and maintains her medical license in Massachusetts. (*Id.*) Dr. Anand's clinical practice focuses on neuroimmunology, neuro-infectious diseases, and acute complications of neurologic disorders. (Ex. A, pp. 1-2.) She frequently treats and evaluates patients with neurologic complications of vaccination. (*Id.* at 2.) Dr. Anand has published 45 peer-reviewed articles on various topics in neurology, many of which focus on the neurologic complications of autoimmune and infectious disorders. (*Id.*)

"longstanding" diabetic polyneuropathy preceding the vaccination at issue. (*Id*. at 3.) She opines that petitioner's post-vaccination symptoms are more likely attributable to progression of his diabetic polyneuropathy. (*Id.*) She indicates there is no conclusive evidence to support a CIDP diagnosis. (*Id*.) But, in any event, Dr. Anand opines based on her review of CIDP literature that, even if petitioner did have CIDP, his diabetes would be a more likely cause than his flu vaccine. (*Id*. at 4.)

Dr. Anand explains that half of all diabetes patients will eventually develop diabetic polyneuropathy. (Ex. A, p. 4 (citing P.J. Dyck et al., *The Prevalence by Staged Severity of Various Types of Diabetic Neuropathy, Retinopathy, and Nephropathy in a Population-Based Cohort: The Rochester Diabetic Neuropathy Study*, 43 NEUROLOGY 817 (1993) (Ex. A, Tab 1); Melissa A. Elafros et al., *Towards Prevention of Diabetic Peripheral Neuropathy: Clinical Presentation, Pathogenesis, and New Treatments*, 21 LANCET NEUROLOGY 922 (2022) (Ex. A, Tab 2)).) Risk factors include longer duration of diabetes, higher glycated hemoglobin (hemoglobin A1c) levels, hypertension, and dyslipidemia. (*Id.* (citing Xiuxiu Liu et al., *The Risk Factors for Diabetic Peripheral Neuropathy: A Meta-Analysis*, 12 PLOS ONE e0212574 (2019) (Ex. A, Tab 3); Heung Yong Jin et al., *The Impact of Glycemic Variability on Diabetic Peripheral Neuropathy*, 53 ENDOCRINE 643 (2016) (Ex. A, Tab 4); Brian C. Callaghan et al., *Metabolic Syndrome Components are Associated with Symptomatic Polyneuropathy Independent of Glycemic Status*, 39 DIABETES CARE 801 (2016) (Ex. A, Tab 5)).) According to Dr. Anand, petitioner had all of these risk factors, including a 16-year history of diabetes, high A1c of up to 12% (with 5.7% being the upper threshold of normal), and comorbid hypertension and dyslipidemia. (*Id*.)

Further, Dr. Anand explains that petitioner meets the published guidelines for diagnosis of diabetic polyneuropathy by the American Diabetes Association. (Ex. A, p. 4.) Specifically: symptoms of numbness, tingling, and poor balance, coupled with physical exam findings of either absent ankle reflexes, reduced or absent vibration perception, reduced or absent proprioceptive sensation, and pressure ulcers). (*Id*. (citing Rodica Pop-Busui et al., *Diabetic Neuropathy: A Position Statement by the American Diabetes Association*, 40 DIABETES CARE 136 (2017) (Ex. A, Tab 6)).) Consistent with petitioner's post-vaccination presentation, diabetic polyneuropathy can present with absent reflexes and proximally ascending loss of sensation, which can be either length-dependent or in a stocking-glove distribution. (*Id*.)

Based on her review of the records, Dr. Anand concludes that petitioner has carried a diagnosis of severe diabetic peripheral neuropathy since at least November 2015, more than four years prior to the December 2019 vaccination at issue. (Ex. A, p. 5 (citing Ex. 7, p. 27).) Additionally, around that time, petitioner had a painless diabetic foot ulcer, which is often caused by diabetic polyneuropathy. (*Id*. (citing Agbor Ndip et al., *Neuropathic Diabetic Foot Ulcers – Evidence-to-Practice*, 5 INT'L J. GEN. MED. 129 (2012) (Ex. A, Tab 12)).) Although the records are unavailable, Dr. Anand surmises that diabetic polyneuropathy is the most likely reason for petitioner's prior 2012 electrodiagnostic testing. (*Id*.) And, notably, petitioner reported worsening of his polyneuropathy a month prior to vaccination. (*Id.*) At that time, petitioner was

recovering from cardiac surgery and Dr. Scott noted that postoperatively he had developed rapidly progressive weakness, numbness, and muscle atrophy, of both the upper and lower extremities. (*Id*. (citing Ex. 5, p. 3007).) Accordingly, Dr. Anand does not agree that there is a temporal relationship between petitioner's condition and his vaccination.

Dr. Anand notes Dr. Scott's assessment of petitioner's condition as being "complex" with features of both diabetic polyneuropathy and CIDP (Ex. A, p. 4 (citing Ex. 5, p. 3007)); however, she stresses his observation that petitioner's condition improved not only with immunomodulatory therapy, but also with improved glucose control. (*Id.*) She further explains that diabetic nerve pathology can demonstrate both axonal and demyelinating features on electrodiagnostic study. (*Id*. (citing J. Valls-Canals et al., *Diabetic Polyneuropathy: Axonal or Demyelinating?*, 42 ELECTROMYOGRAPHY & CLINICAL NEUROPHYSIOLOGY 3 (2002) (Ex. A, Tab 7); Khema R. Sharma et al., *Demyelinating Neuropathy in Diabetes Mellitus*, 59 ARCHIVES NEUROLOGY 758 (2002) (Ex. A, Tab 8)).) Thus, she contends that diabetic neuropathy alone can explain petitioner's 2021 EMG results.[13] (*Id*. (citing Ex. 5).) She notes that a nerve biopsy or cerebrospinal fluid analysis could have helped differentiate between diabetic neuropathy and CIDP, but these tests were not performed. (*Id*. at 4-5.) Dr. Anand indicates that CIDP is a challenging diagnosis to make, with no reliable biologic marker, and it is "commonly" misdiagnosed, especially among diabetic patients who do not have a nerve biopsy completed. (*Id*. at 5 (citing D.R. Cornblath et al., *Research Criteria for Diagnosis of Chronic Inflammatory Demyelinating Polyneuropathy (CIDP)*, 41 NEUROLOGY 617 (1991) (Ex. A, Tab 9); Jeffrey A. Allen & Richard A. Lewis, *CIDP Diagnostic Pitfalls & Perception of Treatment Benefit*, 85 NEUROLOGY 498 (2015) (Ex. A, Tab 10)).)

Dr. Anand disagrees that evidence pertaining to the flu vaccine as a cause of GBS can be extended to CIDP. (Ex. A, pp. 5-6.) According to Dr. Anand, "multiple studies suggest that the rate of antecedent vaccination in patients with CIDP is equal to that of historical control groups and is consistently lower than those reported in studies on Guillain-Barre syndrome, suggesting that, unlike Guillain-Barre syndrome, antecedent vaccination is unlikely to play a role in the risk of CIDP." (*Id*. at 6 (citing P.E. Doneddu et al., *Risk Factors for Chronic Inflammatory Demyelinating Polyradiculoneuropathy (CIDP): Antecedent Events, Lifestyle and Dietary Habits. Data from the Italian Database*, 27 EUR. J. NEUROLOGY 136 (2020) (Ex. A, Tab 16)).) By contrast, multiple studies have shown that the risk of CIDP among diabetes patients is more than twice as high as the general population. (*Id*. (citing Sharma et al., *supra*, at Ex. A, Tab 8; Satoshi Kuwabara et al., *Chronic Inflammatory Demyelinating Polyneuropathy & Diabetes*, 91 J. NEUROLOGY, NEUROSURGERY, & PSYCHIATRY 1035 (2020) (Ex. A, Tab 17); Helmar Christoph Lehmann et al., *Chronic Inflammatory*

[13] Dr. Anand noted that the medical records additionally reference prior electrodiagnostic studies from 2012 and 2020 that were not available within the medical records that had been filed. (Ex. A, p. 4.) Subsequent to the filing of Dr. Anand's report, petitioner filed additional records including the 2020 electrodiagnostic study. (Ex. 11.)

Demyelinating Polyneuropathy: Update on Diagnosis, Immunopathogenesis & Treatment, 90 J. NEUROLOGY, NEUROSURGERY, & PSYCHIATRY 981 (2019) (Ex. A, Tab 18); P.Y.K. Van den Bergh et al., *European of Neurological Societies/Peripheral Nerve Society Guideline on Management of Chronic Inflammatory Demyelinating Polyradiculoneuropathy: Report of Joint Task Force of the Eur. Federation of Neurological Societies & Peripheral Nerve Society – First Revision*, 17 EUR. J. NEUROLOGY 356 (2010) (Ex. A, Tab 19); Yusuf A. Rajabally et al., *Chronic Inflammatory Demyelinating Polyneuropathy Associated with Diabetes: A European Multicentre Comparative Reappraisal*, 91 J. NEUROLOGY, NEUROSURGERY, & PSYCHIATRY 1100 (2020) (Ex. A, Tab 20)).)

Dr. Anand explains that

> CIDP is an autoimmune or inflammatory neuropathy caused by an overactive immune system attacking a patient's peripheral nerves. Patients with type 2 diabetes have increased activation of inflammatory factors in their peripheral nerves, which may facilitate the development of CIDP. Pre-existing nerve breakdown due to diabetic polyneuropathy may further prime the immune system to attack the peripheral nerves. Finally, patients with diabetes have dysregulation of the blood vessels feeding their peripheral nerves, which may disrupt the blood-nerve barrier and lead to inflammation.

(Ex. A, p. 6.)

c. Petitioner's General and Vascular Surgery Expert, Garry Ruben, M.D.[14]

Dr. Ruben opines that respondent's expert inappropriately "discounts the rapid onset of symptoms and the severity of those symptoms." (Ex. 26, p. 2.) In contrast, he indicates that diabetic neuropathy is a disease of slow and insidious onset, beginning with minimal sensory changes, difficulty with proprioception, and numbness, that later progress to pain and discomfort over a long period of time. (*Id*.) In this case, he disagrees that there is any evidence of neuropathy prior to the vaccination at issue. (*Id*.) Dr. Ruben disagrees that petitioner's prior diabetic foot ulcer, which was noted four

[14] Dr. Ruben earned his medical degree from the University of Maryland School of Medicine in 1977. (Ex. 27, p. 1.) He went on to complete his surgical internship and residency at the University of Pennsylvania in 1978 and 1982 respectively. (*Id.*) In 1984, Dr. Ruben completed his fellowship in peripheral vascular surgery at the Albert Einstein Medical Center in Philadelphia, Pennsylvania. (*Id.* at 2.) Since completing his fellowship, Dr. Ruben has held various academic appointments, including professorships at the University of Pennsylvania School of Medicine and George Washington University School of Medicine. (*Id.*) Currently, Dr. Ruben serves as an associate clinical professor of surgery at George Washington School of Medicine and as the Chief of Vascular Surgery and Director of Surgical Education at Holy Cross Hospital in Silver Spring, Maryland. (*Id.*; Ex. 26, p. 1.) He is board certified in surgery and maintains his medical license in Maryland. (Ex. 27, pp. 2, 4.) In his clinical practice, Dr. Ruben has evaluated and treated a large number of patients with symptoms of neuropathy and a diagnosis of diabetic neuropathy. (Ex. 26, p. 1.) He has co-authored a handful of articles on various surgical topics. (Ex. 27, pp. 6-7.)

years prior to vaccination, is any indication of the presence of a diabetic neuropathy, suggesting that if the ulcer were related to neuropathy, then further tissue loss would be expected. (*Id.*) Dr. Ruben opines that

> [t]he rapid progression and severity of symptoms experienced by [petitioner] within months of his exposure to the vaccine administration clearly point to the vaccine as the most likely cause of the patient's neurologic injury. While he may have a component of diabetic small vessel disease, it was the vaccine that caused the severe symptoms from which he now suffers.

(*Id*.) Dr. Ruben did not cite any literature in connection with his report.

V. Party Contentions

In his motion, petitioner stresses that he experienced difficulty walking and loss of sensation in his hands within three weeks of his December 19, 2019 flu vaccination and that he was eventually diagnosed by his treating neurologist as suffering from CIDP. (ECF No. 67, p. 3.) However, given that other treating physicians had diagnosed GBS, and given that his expert explains that GBS and CIDP symptoms can overlap, petitioner contends that he initially suffered GBS that "morphed into CIDP over time." (*Id*. (citing Ex. 5, p. 783).) Petitioner acknowledges that both parties' experts agree that he was suffering from diabetic neuropathy prior to vaccination; however, he argues that respondent's expert has not justified the assertion that CIDP was misdiagnosed in this case. (*Id.* at 4-5.) Additionally, although respondent's expert theorizes that diabetes can result in CIDP, petitioner argues that this does not account for the fact that his symptoms developed post-vaccination and, even if diabetes can contribute to CIDP, that would not preclude the vaccination from being an additional causal factor. (*Id*. (citing *Shyface*, 165 F.3d at 1352).) Petitioner asserts that this case represents a "battle of the experts" in which the experts differ only on the relative likelihood that petitioner's condition was caused by either his flu vaccine or his diabetes. (*Id*. at 4, 6.)

In response, respondent contends as an initial matter that his expert, Dr. Anand, is better qualified to opine in this case than petitioner's expert, Dr. Shuper. (ECF No. 69, pp. 10, 12.) Moreover, he contends that petitioner's other expert, Dr. Ruben, is not qualified to opine at all. (*Id.* at 10-12.) Respondent indicates that petitioner's argument that he suffers CIDP standing alone prevents him from demonstrating the presence of a Table Injury of GBS. (*Id*. at 14 (citing 42 C.F.R. § 100.3(c)(15)(vi) for the proposition that diagnosis of CIDP is an exclusionary criterion for GBS).) However, given respondent's assessment that petitioner suffered preexisting diabetic neuropathy, respondent also argues that petitioner cannot establish that his symptoms first occurred between 3-42 days post-vaccination or that they constituted a monophasic illness with nadir occurring within 28 days. (*Id*. at 13.) And, in any event, the diabetic neuropathy represents a more likely alternative diagnosis. (*Id*.) Regarding causation in fact, respondent argues that, because petitioner's condition is better explained as diabetic neuropathy, it is not even necessary to reach the *Althen* test with respect to petitioner's alleged CIDP. (*Id*. at 18-21.) However, if the court were to conclude petitioner suffered

CIDP, respondent argues that petitioner has not demonstrated a theory of vaccine causation under *Althen* prong one and that his diabetes would still be a more likely cause of his CIDP under *Althen* prong two. (*Id*. at 22-30.) With respect to *Althen* prong three, respondent disputes the temporal association petitioner seeks to draw, again stressing his preexisting diabetic neuropathy. (*Id*. at 30-31.)

In reply, petitioner notes that, as a neurologist Dr. Shuper is qualified to opine in this case and that ultimately "the soundness of the reasoning supporting the arguments put forth by the Petitioner's experts" should carry greater weight." (ECF No. 70, pp. 1-2.) Petitioner contends that

> any number of causes *could* explain a neuropathic disorder, as the vague nature of these disorders typically robs us of any certain diagnosis. If certainty were the VICP standard, very few cases would be filed in this Court. But the issue is not whether CIDP is clearly or certainly the better casual explanation than diabetic neuropathy, or whether CIDP is the only possible causal explanation for the petitioner's symptoms. The issue is merely whether a reasonable enough probability exists that CIDP could have caused or substantially aggravated the petitioner's symptoms.

(*Id*. at 3 (emphasis original).)

VI. Discussion

a. Petitioner's flu vaccination did not cause his CIDP

i. *Althen* prong one

Under *Althen* prong one, petitioners must provide a "reputable medical theory," demonstrating that the vaccine received can cause the type of injury alleged. *Pafford v. Sec'y of Health & Human Servs.*, 451 F.3d 1352, 1355-56 (Fed. Cir. 2006) (quoting *Pafford v. Sec'y of Health & Human Servs.*, No. 01-0165V, 2004 WL 1717359, at *4 (Fed. Cl. Spec. Mstr. July 16, 2004)). Such a theory must only be "legally probable, not medically or scientifically certain." *Knudsen v. Sec'y of Health & Human Servs.*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). Petitioners may satisfy the first *Althen* prong without resort to medical literature, epidemiological studies, demonstration of a specific mechanism, or a generally accepted medical theory. *See Andreu v. Sec'y of Health & Human Servs.*, 569 F.3d 1367, 1378 (Fed. Cir. 2009) (citing *Capizzano v. Sec'y of Health & Human Servs.*, 440 F.3d 1317, 1325-26 (Fed. Cir. 2006)). However, "[a] petitioner must provide a 'reputable medical or scientific explanation' for [their] theory." *Boatmon*, 941 F.3d at 1359 (quoting *Moberly v. Sec'y of Health & Human Servs.*, 592 F.3d 1315, 1322 (Fed. Cir. 2010)). "While it does not require medical or scientific certainty, it must still be 'sound and reliable.'" *Id.* (quoting *Knudsen*, 35 F.3d at 548-49).

Dr. Shuper provides very little that could potentially support a reliable theory of causation under *Althen* prong one relative to CIDP. In fact, he acknowledges that it

remains unproven how a vaccine could cause any inflammatory neuropathy (Ex. 10, p. 11), and provides no direct evidence even purporting to implicate the flu vaccine as a cause of CIDP. Instead, his opinion rests primarily on two points: (1) CIDP may exist on a "spectrum" of inflammatory neuropathies along with GBS and GBS, in turn, can be shown to be caused by the flu vaccine; and (2) peripheral nerve damage, including demyelination, can occur as a result of molecular mimicry between a foreign antigen and gangliosides, as is seen, for example, with respect to campylobacter jejuni. (*Id.* at 4-6, 9-10.) In effect, these two points are both meant to support a single assertion – that the causes and immune pathology of GBS should be viewed as likewise applying to CIDP. However, this is not persuasive without more. *E.g. Nieves v. Sec'y of Health & Human Servs*., No. 18-1602V, 2023 WL 3580148, at *35 (Fed. Cl. Spec. Mstr. May 22, 2023) (explaining that "it is facile (for purposes of deciding entitlement in Program cases) to characterize CIDP as merely 'long GBS' . . . [t]he two diseases are distinguishable not only in their course and treatment, but also in the inciting events that cause them – even if both are mediated by autoimmune processes.").

Molecular mimicry, as Dr. Shuper invokes, "is a generally accepted scientific principle, [but] mere invocation of the scientific term does not carry a petitioner's burden in a Program case." *Deshler v. Sec'y of Health & Human Servs*., No. 16-1070V, 2020 WL 4593162, at *20 (Fed. Cl. Spec. Mstr. July 1, 2020) (citing *Forrest v. Sec'y of Health & Human Servs.*, No. 14-1046V, 2019 WL 925495, at *3 (Fed. Cl. Spec. Mstr. Jan. 28, 2019)). Dr. Shuper's presentation of molecular mimicry is limited to demonstrating that it is a viable explanation as to how campylobacter jejuni can cause GBS. (*See* Ex. 10, pp. 9-10.) However, molecular mimicry is a context specific concept that requires a match (or homology) between a specific foreign antigen and a particular bodily tissue such that the immune system can cross-react against the bodily tissue. The fact that campylobacter jejuni can lead to cross-reaction against nerve tissue, though not wholly irrelevant at a broad level, does not demonstrate that an entirely unrelated antigen, such as would be contained in the flu vaccine, would do the same.[15] Moreover, although

[15] Even where a petitioner demonstrates a homology as a first step in demonstrating molecular mimicry, "the finding of sequence homology does not necessarily mean the similarity has significance to the immune system." *Tullio v. Sec'y of Health & Human Servs.*, No. 15-51V, 2019 WL 7580149, at *15 (Fed. Cl. Spec. Mstr. Dec. 19, 2019), *aff'd*, 149 Fed. Cl. 448 (2020); *see also Caredio v. Sec'y of Health & Human Servs.*, No. 17-0079V, 2021 WL 4100294, at *31 (Fed. Cl. Spec. Mstr. July 30, 2021) ("*[D]emonstration of homology alone is not enough to establish a preponderant causation theory.*") (citing *Schultz v. Sec'y of Health & Human Servs.*, No. 16-539V, 2020 WL 1039161, at *22 n.24 (Fed. Cl. Spec. Mstr. Jan. 24, 2020)), *mot. for rev. den'd*, 2021 WL 6058835 (Fed. Cl. Dec. 3, 2021). Of course, petitioners in this program are not required to establish scientific certainty. Prior cases have expressed with regard to the application of molecular mimicry that "[t]he line must be drawn somewhere between speculation and certainty." *Brayboy v. Sec'y of Health & Human Servs.*, No. 15-183V, 2021 WL 4453146, at *19 (Fed. Cl. Spec. Mstr. Aug. 30, 2021). Thus, for example, in *Brayboy*, an omnibus proceeding addressing autoimmune premature ovarian insufficiency, the special master found it sufficient that the petitioners "identified cross-reaction between components of the vaccine and proteins in the body that are directly responsible for the health and productivity of the organ at issue" and further expressed that requiring additional steps, or insisting on direct, testable evidence, would impermissibly heighten petitioners' burden of proof. *Id.*

campylobacter jejuni can be associated with GBS, Dr. Shuper has not established that it is an important cause of CIDP.

The literature Dr. Shuper cites explains that "[c]ampylobacter jejuni gastroenteritis and antiganglioside antibodies correlate with axonal damage and a poorer prognosis in adult GBS." (Malcolm Rabie & Yorman Nevo, *Childhood Acute & Chronic Immune-Mediated Polyradiculoneuropathies*, 13 EUR. J. PAEDIATRIC NEUROLOGY 209 (2009) (Ex. 15, p. 3).) Various antibodies to gangliosides are found in patients suffering certain forms of GBS. (*Id*.) However, the same literature indicates that CIDP is thought to be primarily a T-cell mediated condition, with no identified antibodies in children and a candidate autoantigen being proposed in only 20% of adults. (*Id.*) That candidate (P0 myelin protein) is distinct from the ganglioside antibodies identified in GBS. (*Id*.) Therefore, the literature upon which Dr. Shuper relies, while acknowledging GBS and CIDP to be related, nonetheless distinguishes the underlying immune pathology in a manner that defies Dr. Shuper's intimation that the causes of the two conditions can be treated as interchangeable. *Accord Houston v. Sec'y of Health & Human Servs*., No.18-420V, 2021 WL 4259012, at *16 (Fed. Cl. Spec. Mstr. Aug. 19, 2021) (observing that "while it is believed that certain autoantibodies specific for amino acid sequences found in myelin basic protein may be a source of the autoimmune attack resulting in GBS, 'antibodies against peripheral nerve myelin proteins . . . are too infrequently detected in the sera of CIDP patients to be considered pathogenic or molecular markers of disease.'").

In sum, while molecular mimicry is a valid concept in general, and while the flu vaccine can separately be shown to be a cause of GBS, nothing on this record apart from Dr. Shuper's *ipse dixit* evidences molecular mimicry as a theory to explain how the flu vaccine could likewise cause CIDP. Moreover, Dr. Anand challenges Dr. Shuper's bare assertion, opining that there is a lack of evidence to support the contention that the flu vaccine is an important antecedent event to CIDP in the same manner as GBS. (Ex. A, pp. 5-6.) Thus, petitioner has not presented preponderant evidence supporting the idea that the flu vaccine can be considered among the causes of CIDP.

ii. *Althen* prong two

The second *Althen* prong requires proof of a logical sequence of cause and effect, usually supported by facts derived from a petitioner's medical records. *Althen*, 418 F.3d at 1278; *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326-27; *Grant*, 956 F.2d at 1147-48. Medical records are generally viewed as particularly trustworthy evidence. *Cucuras*, 993 F.2d at 1528. However, medical records and/or statements of a treating physician's views do not *per se* bind the special master. *See* § 300aa-13(b)(1) (providing that "[a]ny such diagnosis, conclusion, judgment, test result, report, or summary shall not be binding on the special master or court"); *Snyder v. Sec'y of Health & Human Servs.*, 88 Fed. Cl. 706, 745 n.67 (2009) ("[T]here is nothing . . . that mandates that the testimony of a treating physician is sacrosanct—that it must be accepted in its entirety and cannot be rebutted."). A petitioner may support a cause-in-fact claim through either medical records or expert medical opinion. § 300aa-13(a).

The special master is required to consider all the relevant evidence of record, draw plausible inferences, and articulate a rational basis for the decision. *Winkler*, 88 F.4th at 963 (citing *Hines*, 940 F.2d at 1528).

The parties present a close threshold question as to whether petitioner actually had CIDP at all or whether his condition is explained entirely by his preexisting diabetic neuropathy. Ultimately, however, Dr. Anand opines on respondent's behalf that CIDP "cannot be entirely ruled out." (Ex. A, pp. 3-4.) Moreover, petitioner's treating neurologist, Dr. Scott, was careful to note that petitioner's presentation was "complex" and ultimately came to the conclusion that it was "multifactorial." (Ex. 5, p. 3007.) Based on his history and presentation, electrodiagnostic studies, and response to treatment, Dr. Scott ultimately concluded that petitioner suffered CIDP additional to his preexisting diabetic neuropathy. (*Id*.) In particular, Dr. Scott specifically concluded that, while his sensory loss was due to a combination of both CIDP and diabetes, petitioner's muscle weakness and atrophy was due to CIDP. (*Id*. at 3011.) The opinions and views of a petitioner's treating physicians generally garner significant weight. *Andreu*, 569 F.3d at 1375-77; *Capizzano*, 440 F.3d at 1326. Especially given the closeness of the question as acknowledged by respondent's expert, there is little reason to disregard the opinion of petitioner's treating neurologist. Accordingly, there is preponderant evidence that petitioner suffered CIDP.

This leaves the key remaining question as whether there is preponderant evidence that petitioner's flu vaccination was a cause of his CIDP. There are several reasons why such an assertion is not preponderantly supported. First, petitioner's medical records place the onset of his symptoms as occurring prior to the vaccination at issue. Second, and relatedly, his assertion in this case of a post-vaccination onset of symptoms appears to be based on a mistaken belief as to the date of his vaccination. Overall, his statements favor a pre-vaccination onset and, in any event, lack the consistency necessary to outweigh the contemporaneous records. Third, given the first two issues, petitioner's expert medical opinions regarding vaccine causation are ultimately based on faulty factual assumptions regarding onset. Fourth, consistent with the analysis under *Althen* prong one, there is not otherwise any medical opinion within petitioner's medical records supporting vaccine causation of CIDP. And, fifth, regardless of whether diabetes is a cause of CIDP *per se*, both parties' experts acknowledge that diabetes patients are at elevated risk of developing CIDP, meaning that there is little need to invoke petitioner's vaccination to explain his condition.

1) Treatment records place onset of CIDP pre-vaccination

When petitioner first sought care for symptoms of what would eventually be diagnosed as CIDP, he reported to his cardiologist in February of 2020 that "[s]ince surgery, he has noted vague weakness in both hands." (Ex. 5, p. 1244.) The cardiologist referred him to neurology and he subsequently had a full neurologic evaluation in June of 2020. (*Id*. at 1120.) In connection with that evaluation, petitioner reported that he was "in his usual state of health until November 2019 when he

underwent cardiac surgery. Postoperatively, he developed rapidly progressive weakness, numbness, and muscle atrophy of the upper and lower extremities." (*Id.*)

These histories, which clearly place the onset of petitioner's alleged CIDP prior to his December 19, 2019 flu vaccination, carry significant weight for multiple reasons. They are records created by persons disinterested in this litigation. They are contemporaneous to treatment, which generally positions them as reflective of the earliest available recollection of events. And, finally, they are offered for purposes of diagnosis and treatment, which provides an incentive for accuracy. *Cucuras*, 993 F.2d at 1528 (explaining that "medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to medical events."); *Reusser v. Sec'y of Health & Human Servs.*, 28 Fed. Cl. 516, 523 (1993) (observing "the widely held belief that written documentation recorded by a disinterested person at or soon after the event at issue is generally more reliable than the recollection of a party to a lawsuit many years later.")

2) Petitioner's statements do not outweigh the medical records

Despite the above, petitioner asserts in several written statements that his symptoms occurred post-vaccination. When witness testimony is offered to overcome the weight afforded to contemporaneous medical records, such testimony must be "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Human Servs.*, 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Human Servs.*, No. 90-2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)). Further, the special master must consider the credibility of the individual offering the testimony. *Andreu*, 569 F.3d at 1379; *Bradley v. Sec'y of Health & Human Servs.*, 991 F.2d 1570, 1575 (Fed. Cir. 1993). In determining whether to afford greater weight to contemporaneous medical records or other evidence, such as testimony, there must be evidence that this decision was the result of a rational determination. *Burns v. Sec'y of Health & Human Servs.*, 3 F.3d 415, 416-17 (Fed. Cir. 1993). The special master is obligated to consider and compare the medical records, testimony, and all other "relevant and reliable evidence" contained in the record. *La Londe v. Sec'y Health & Human Servs.*, 110 Fed. Cl. 184, 204 (2013) (citing § 300aa-12(d)(3); Vaccine Rule 8), *aff'd sub nom. LaLonde v. Sec'y of Health & Human Servs.*, 746 F.3d 1334 (Fed. Cir. 2014); *see also Burns*, 3 F.3d at 417.

In his statement from February of 2021, which is his only sworn statement in the case, petitioner specifically recalled that the symptoms of his alleged CIDP began during his post-operative physical therapy following his November 4, 2019 cardiac surgery. (ECF No. 27). In his final statement from April of 2023, he further confirmed that his post-operative rehabilitation began on November 19, 2019 and that his symptoms were present within two and a half weeks of beginning rehabilitation. (Ex. 12.) Consistent with the above discussed medical records, these statements place

onset of petitioner's condition in the context of his post-surgical recovery and sometime during the first two weeks of December. However, the reason petitioner asserted that he experienced his symptoms post-vaccination is because these statements mis-recalled the date of vaccination, with petitioner stating that he believed he had been vaccinated on November 14, 2019, the last day of his hospitalization. (*Compare* ECF No. 27, Ex. 12 *with* Ex. 6.) Thus, these two statements by petitioner, which are the more detailed statements as to the timing of symptom onset, actually further support the pre-vaccination onset described within the contemporaneous medical records.

Two additional statements by petitioner are less compelling. A statement by petitioner filed in January of 2022 seeks to amend petitioner's understanding of the date of his vaccination, correctly stating that he was vaccinated on December 19, 2019; however, that statement merely states that petitioner was in "good health" when he received his vaccination. (ECF No. 31.) That statement does not appear reliable, both because it is contradicted by petitioner's earlier, more detailed, account of the onset of his condition and because the medical records also otherwise show that "good health," which is vague in itself, is a poor description of petitioner's health at the time he received his vaccination. Rather, even setting aside his CIDP, he was recently recovering from a cardiac surgery and was suffering from diabetes significant enough to result in diabetic neuropathy and neurotrophic foot ulcers. (Ex. 7, p. 2; Ex. 8, p. 116; Ex. 9, pp. 1120, 1549.) Finally, an additional statement, contained within Dr. Shuper's report, indicates that symptoms consistent with CIDP arose post-vaccination, but this statement does not identify the date of vaccination or contain any detail that would otherwise date the onset of symptoms. (Ex. 10, p. 7.)

Given petitioner's inconsistent recollection of the date of his vaccination, these four statements as a body of evidence lack the consistency and cogency necessary to outweigh the histories recorded in the contemporaneous medical records. But in any event, those aspects of these statements that agree with a pre-vaccination onset of CIDP are clearer and more compelling than those that would seek to refute it. Accordingly, considering the record as a whole, and balancing the contemporaneous medical records and petitioner's statements, the evidence preponderates in favor of an onset of CIDP occurring prior to petitioner's flu vaccination on December 19, 2019.

3) Petitioner's experts reply on incorrect factual assumptions

In opining that petitioner suffered vaccine-caused CIDP, his expert, Dr. Shuper, specified that he based his causal opinion on four considerations, two of which relate to identifying the symptoms of petitioner's CIDP as occurring post-vaccination. (Ex. 10, pp. 7-9.) In particular, he relied on the idea that petitioner's pre- and post-vaccination symptoms were distinct and that a "short time interval" between petitioner's vaccination and the appearance of CIDP as the "first indication of a causal connection." (*Id.* at 7-8.) These assessments are in turn informed by petitioner's narrative account of the onset of his condition as well as his complaints as presented at his February 2020 cardiology follow up. (*Id*. (citing Ex. 5, p. 1244).) Significantly, however, when petitioner first reported a new symptom of hand weakness to his cardiologist in February of 2020, as

cited by Dr. Shuper, he specifically stated that he had experienced this symptom "since surgery." (Ex. 5, p. 1244.) Moreover, for the reasons discussed above, petitioner's statements likewise favor a pre-vaccination onset of CIDP symptoms. Accordingly, Dr. Shuper's opinion is premised on a faulty assumption as to the onset of symptoms consistent with CIDP.

Additionally, Dr. Ruben's assertion that there is "no evidence" of neuropathy prior to immunization is simply not credible.[16] (Ex. 26, p. 2.) Multiple medical records confirm that petitioner was diagnosed with "severe" diabetic peripheral neuropathy prior to vaccination. (Ex. 7, pp. 2, 9, 28; Ex. 8, pp. 123, 140, 154, 174, 181, 193, 202, 211, 220, 233.) Moreover, petitioner's other expert, Dr. Shuper, agrees that petitioner was experiencing foot numbness in September of 2019. (Ex. 10, p. 8 (citing Ex. 5, p. 576.) And, while Dr. Ruben seeks, with minimal explanation, to discount the significance of petitioner's diabetic ulcers as evidence of neuropathy (Ex. 26, p. 2), the medical records explicitly diagnose petitioner's foot ulcer as neurotrophic. (Ex. 7, pp. 2, 8-10, 12, 26-28.)

Accordingly, neither of petitioner's experts' casual opinions is credited. *Burns*, 3 F.3d at 417 (holding that "[t]he special master concluded that the expert based his opinion on facts not substantiated by the record. As a result, the special master properly rejected the testimony of petitioner's medical expert."); *see also Rickett v. Sec'y of Health & Human Servs.,* 468 F. App'x 952, 958 (Fed. Cir. 2011) (holding that "it was not error for the Special Master to assign less weight to Dr. Bellanti's conclusion regarding challenge-rechallenge to the extent it hinged upon Mr. Rickett's testimony that was inconsistent with the medical records"); *Dobrydnev v. Sec'y of Health & Human Servs.,* 566 F. App'x 976, 982-83 (Fed. Cir. 2014) (holding that the special master was correct in noting that "when an expert assumes facts that are not supported by a preponderance of the evidence, a finder of fact may properly reject the expert's

[16] A special master may properly evaluate, and give appropriate weight to, whether certain testimony is beyond a particular expert's purview. *See, e.g.*, *King v. Sec'y of Health & Human Servs.*, No. 03-584V, 2010 WL 892296, at *78-79 (Fed. Cl. Spec. Mstr. Mar. 12, 2010) (finding petitioner's expert far less qualified to offer opinion on general causation issues pertaining to autism than specific issues pertaining to the petitioner's actual medical history, given the nature of the expert's qualifications). In that regard, respondent argues that Dr. Ruben lacks sufficient qualifications to even offer an opinion on the issues in this case. (ECF No. 69, pp. 10-11.) I cannot fully agree. Although respondent is obviously correct that Dr. Ruben is not a neurologist, he is a vascular surgeon and represents that he has treated a large number of patients with diabetic neuropathy and/or symptoms of neuropathy. (Ex. 26, p. 1.) Respondent's own expert indicates that diabetic neuropathy implicates "dysregulation of the blood vessels feeding their peripheral nerves." (Ex. A, p. 6.) Accordingly, on this record, there is no readily apparent basis for doubting Dr. Ruben's representation that he treats patients with diabetic neuropathy. And, while I do agree that the neurologists' opinions carry greater weight overall and especially with respect to CIDP, Dr. Ruben's report is primarily focused on the characteristics of diabetic neuropathy. (*See* Ex. 26.) Dr. Ruben's status as a medical doctor renders him at least minimally qualified to render a medical opinion. *E.g. Ruzicka v. Sec'y of Health & Human Servs.*, No. 17-109V, 2023 WL 8352496, at *17 (Fed. Cl. Spec. Mstr. Nov. 13, 2023) (finding petitioner's experts unpersuasive as to neurology and immunology given his qualifications, but nonetheless qualified to opine on medical matters generally). In any event, it is not ultimately necessary to definitively resolve the scope of Dr. Ruben's purview as an expert, because his key observation as discussed herein lacks credibility as a basic interpretation of the record evidence regardless of his qualifications.

opinion") (citing *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp*., 509 U.S. 209, 242 (1993)); *Bushnell v. Sec'y of Health & Human Servs.,* No. 02-1648V, 2015 WL 4099824, at *12 (Fed. Cl. Spec. Mstr. June 12, 2015) (finding that "because Dr. Marks' opinion is based on a false assumption regarding the onset of J.R.B.'s condition, and the incorrect assumption of a 'stepwise regression' after each vaccine administration, it should not be credited").

4) Petitioner's treating physicians did not opine that his CIDP was vaccine-caused

Absent his experts' causal assessments, petitioner's medical records do not otherwise contain any medical opinion sufficient to carry his burden of proof. Petitioner cites only one notation by his primary care provider, Dr. Whittington, as suggesting petitioner's condition was vaccine-caused.[17] (ECF No. 67, p. 3 (citing Ex. 5, p. 783).) However, that particular notation was made with specific respect to GBS (Ex. 5, p. 783), which, as explained under *Althen* prong one, cannot be equated with CIDP for purposes of assessing vaccine causation. While it is generally accepted that the flu vaccine can cause GBS (*see* 42. C.F.R. 100.3(a)(XIV)(D)), petitioner has not shown by preponderant evidence that the flu vaccine causes CIDP. None of petitioner's medical records contain a medical opinion supporting the notion that the flu vaccine can or did cause CIDP.

5) Petitioner was at heightened risk of developing CIDP due to his diabetes

Finally, although respondent's expert, Dr. Anand, preferred a diagnosis of diabetic polyneuropathy, she also opined that, if petitioner had CIDP, then his diabetes would be the most likely cause of his CIDP. (Ex. A, p. 4.) Although Dr. Shuper did not reach the same conclusion, he acknowledged that "I can understand if other expert witnesses review the same evidence and come away with the conclusion that diabetes, or some other condition, played a more substantial rose in causing [petitioner's] CIDP to develop." (Ex. 10, p. 9.) Moreover, Dr. Shuper cited literature demonstrating increased incidences of CIDP among diabetic patients. (*Id.* at 11-13 (citing Vital et al., *supra*, at Ex. 17; Rotta et al., *supra*, at Ex. 18; Lozeron et al., *supra*, at Ex. 19; Sharma et al., *supra*, at Ex. 20; Rajabally et al., *supra*, at Ex. 21; Mahdi-Rogers & Hughes, *supra*, at Ex. 22; Bril et al., *supra*, at Ex. 23; Rajabally et al., *supra*, at Ex. 25).) Thus, he agreed that the association is "well-founded." (*Id.* at 13.) Although Dr. Shuper opined that only

[17] Although the specific notation at issue merely states that petitioner's condition followed vaccination, rather than explicitly being caused by vaccination (Ex. 5, p. 783), his medical records otherwise indicate that the flu vaccine was added to his allergy list. (*Id.* at 765, 779.) Accordingly, this could potentially be *some* indication that a causal relationship was accepted, but not necessarily. *Andreu*, 569 F.3d at 1376 (indicating that "[a] treating doctor's recommendation to withhold a particular vaccination can provide probative evidence of a causal link between the vaccination and an injury a claimant has sustained."); *but see Matthews v. Sec'y of Health and Human Servs*., No. 19-414V, 2021 WL 4190265, at * (Fed. Cl. Spec. Mstr. Aug. 19, 2021) (explaining that "the act of marking something as an allergy or as contraindicated is a precaution against future harm. In that regard, petitioner's GBS need not necessarily have been vaccine-caused to warrant the precaution"), *mot. rev. den'd*, 157 Fed. Cl. 777 (2021).

an association, rather than a causal relationship, has been recognized (*Id.* at 11), Dr. Anand additionally offered a medical explanation to support a causal relationship between diabetes and CIDP. (Ex. A, p. 6.) Specifically, she opined that

> [p]atients with type 2 diabetes have increased activation of inflammatory factors in their peripheral nerves, which may facilitate the development of CIDP. Pre-existing nerve breakdown due to diabetic polyneuropathy may further prime the immune system to attack the peripheral nerves. Finally, patients with diabetes have dysregulation of the blood vessels feeding their peripheral nerves, which may disrupt the blood-nerve barrier and lead to inflammation.

(*Id.*) Nothing in either Dr. Shuper's or Dr. Ruben's reports rebuts this explanation. In any event, although Dr. Shuper considers petitioner's vaccination to be a further contributing cause of petitioner's CIDP given his assumption regarding the course of events, he does not ultimately dispute that petitioner's CIDP was caused at least in part by his diabetes. (Ex. 10, p. 9.)

In light of all of the above, and considering the record as a whole, petitioner has not presented preponderant evidence of a logical sequence of cause and effect implicating his December 19, 2019 flu vaccination as a cause of his condition.[18]

iii. *Althen* prong three

The third *Althen* prong requires establishing a "proximate temporal relationship" between the vaccination and the injury alleged. *Althen*, 418 F.3d at 1278. A petitioner must offer "preponderant proof that the onset of symptoms occurred within a timeframe which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *de Bazan v. Sec'y of Health & Human Servs.*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). However, for the reasons discussed in the preceding section, I found that petitioner's alleged CIDP predated the vaccination at issue.

[18] Petitioner's briefing does additionally raise the prospect of an alternative significant aggravation claim. (ECF No. 70, p. 3.) Dr. Shuper likewise raised this possibility in his expert report. (Ex. 10, p. 9.) However, Dr. Shuper's suggestion of a significant aggravation is not well explained. Dr. Shuper's reference to significant aggravation appears primarily to dispute the notion that preexisting diabetic polyneuropathy would be the *sole* cause of petitioner's condition to the exclusion of the flu vaccine. (*Id.*) Nothing in Dr. Shuper's report suggests that conceptualizing petitioner's condition as one of significant aggravation would change his understanding of, or reliance on, the notion that petitioner suffered "distinct" new symptoms in a "short period of time" following vaccination. (*Id.* at 8, 14.) Of course, the *Loving* test for a significant aggravation claim incorporates the same showing of a "logical sequence of cause and effect" within its fifth prong as is otherwise included in the second prong of the *Althen* test as discussed herein. *Loving*, 86 Fed. Cl. at 144. Given the limits of Dr. Shuper's opinion, the same basic faults as discussed above would prevent petitioner from succeeding under *Loving* prong five. Absent his reliance on a distinct set of symptoms occurring post-vaccination, Dr. Shuper has not otherwise explained how one could reach the conclusion that petitioner's vaccination affected his condition. *Sharpe v. Sec'y of Health & Human Servs.*, 964 F.3d 1072, 1083 (Fed. Cir. 2020) (citing *Locane v. Sec'y of Health & Human Servs*., 685 F.3d 1375 (Fed. Cir. 2012) for the proposition that, while a petitioner is not obligated to prove a preexisting condition is worse than otherwise expected, *Loving* prong three addresses whether a pre-existing "was affected by the vaccination.").

Accordingly, there can be no medically reasonable temporal association. *E.g.*, *L.Z. v. Sec'y of Health & Human Servs.*, No. 14-920V, 2018 WL 5784525, at *18 (Fed. Cl. Spec. Mstr. Aug. 24, 2018) (explaining that "[p]etitioner's direct causation claim cannot succeed, as she cannot demonstrate a vaccine 'caused' an illness predating vaccination"). In any event, satisfaction of *Althen* prong three alone would not permit petitioner to prevail. *Veryzer v. Sec'y of Health & Human Servs.*, 100 Fed. Cl. 344, 356 (2011) (explaining that a "temporal relationship alone will not demonstrate the requisite causal link and that petitioner must posit a medical theory causally connecting the vaccine and injury"), *aff'd per curiam*, 475 F. App'x 765 (Fed. Cir. 2012); *Hibbard v. Sec'y of Health & Human Servs.*, 698 F.3d 1355, 1364-65 (Fed. Cir. 2012) (holding the special master did not err in resolving the case pursuant to *Althen* prong two when respondent conceded that petitioner met *Althen* prong three).

b. Petitioner did not suffer GBS

Dr. Shuper indicated on petitioner's behalf that there is a "close resemblance" between CIDP and GBS. (Ex. 10, p. 6.) He explained them as being two conditions within a spectrum of inflammatory neuropathies and, further, that they can be difficult to distinguish, especially given atypical cases in which GBS can recur or CIDP can have a more acute onset. (*Id.*) However, he has not explained or substantiated his assertion that GBS can "morph" into CIDP. (*Id*. at 14.)

But in any event, Dr. Shuper's suggestion that petitioner's condition "initially presented as GBS and then morphed into CIDP" (Ex. 10, p. 14), is not supported by the medical records. When petitioner and Dr. Shuper state that petitioner was diagnosed with GBS, they cite a single encounter record by Dr. Whittington from December 16, 2020. (Ex. 10, p. 8 (citing Ex. 5, p. 783); ECF No. 67, p. 3 (citing Ex. 5, p. 783).) There are several issues with this. First, the statement regarding GBS does not readily constitute a diagnosis in that it appears in the history or "subjective" portion of the encounter record. (Ex. 5, p. 783.) It states: "Unfortunately patient received a flu vaccine and developed Guillain-Barre syndrome and is being managed by the neurologist." (*Id*.) In contrast, the "assessment and plan" portion of the record indicates that petitioner's diagnosis is CIDP. (*Id*.) Second, Dr. Whittington is petitioner's primary care provider and explicitly indicates the condition is the purview of petitioner's neurologist. However, petitioner's neurologist, Dr. Scott, diagnosed CIDP based on both history and electrodiagnostic testing. (Ex. 5, p. 1120.) Finally, whereas Dr. Whittington's notation occurred in December of 2020 (Ex. 5, p. 783), Dr. Scott first diagnosed CIDP in June of 2020. (Ex. 5, p. 1120.) Accordingly, even if one were prepared to consider Dr. Whittington's note as a competing diagnosis, this does not comport with Dr. Shuper's understanding of the medical records as reflecting a view that the condition evolved from GBS to CIDP. To the contrary, the CIDP diagnosis was rendered first.

Considering the record as a whole, the evidence preponderates in favor of a finding that petitioner was diagnosed with CIDP *rather than* GBS. Accordingly, petitioner is not entitled to a presumption of causation for a Table Injury of GBS.

Although Dr. Shuper characterizes CIDP and GBS as being related, a diagnosis of CIDP is listed among the exclusionary criteria for a Table Injury of GBS. 42 C.F.R. § 100.3(c)(15)(vi).

VII. Conclusion

There is no question that petitioner has suffered and that the events discussed throughout this decision have profoundly affected his life. He has my sympathy and I do not question his sincerity in bringing this claim. However, for all the reasons discussed above, I find that petitioner has not met his burden of proof in this case. Therefore, this case is dismissed.[19]

IT IS SO ORDERED.

s/Daniel T. Horner
Daniel T. Horner
Special Master

[19] In the absence of a timely-filed motion for review of this Decision, the Clerk of the Court shall enter judgment accordingly.